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**IN THE UNITED STATES DISTRICT COURT**

**FOR THE DISTRICT OF ARIZONA**

| | |
|---|---|
| IN RE: Bard IVC Filters Products Liability Litigation | No. 2:15-MD-02641-DGC<br><br>**DEFENDANTS C. R. BARD, INC. AND BARD PERIPHERAL VASCULAR, INC.'S REPLY IN SUPPORT OF MOTION TO EXCLUDE THE OPINIONS OF DAVID KESSLER, M.D. AND MEMORANDUM OF LAW IN SUPPORT**<br><br>(Assigned to the Honorable David G. Campbell)<br><br>**(Oral Argument Requested)** |

## INTRODUCTION

Plaintiffs do nothing to dispel Bard's argument that they intend to utilize Dr. Kessler as Judge, counsel, fact witness, and jury. Their repeated concession that he will

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not give legal opinions rings hollow. The opposition is riddled with overt examples of Dr. Kessler's proposed legal conclusions and jury instructions, such as the representation that he will testify about Bard's "Failure to comply with applicable Federal Regulations." (Pl. Br. at 3.) This stark disconnect confirms that plaintiffs will not abide by their concession and will elicit improper legal conclusions from Dr. Kessler unless the Court excludes the specific testimony at issue. Moreover, Dr. Kessler's equally impermissible factual narrative, speculative and preempted regulatory opinions, and opinions relating to non-regulatory matters for which he is unqualified should likewise be excluded.[1]

## ARGUMENT AND CITATION OF AUTHORITY

### A. The Court Should Hold Plaintiffs To Their Concession That Dr. Kessler Will Not Offer Legal Conclusions Or Instruct the Jury on the Law.

Plaintiffs' recognition that Dr. Kessler is prohibited from offering legal opinions provides no assurance they will not attempt to draw out such testimony at trial. Although Plaintiffs' Opposition states that Dr. Kessler "is not offering legal opinions," (Pl. Br. at 9), it nonetheless reveals their intention to elicit the very testimony they conceded was impermissible:

- Dr. Kessler will opine about Bard's "failure to comply with applicable Federal regulations." (Pl. Br. at 3.)
- The Recovery filter "could not be legally marketed." (*Id.* at 4.)
- "[T]he G2 Filter, which had the Recovery as its predicate, could not have been legally marketed." (*Id.*)
- The Recovery was "an 'adulterated' product under the FDCA." (*Id.*)
- The G2 filter "was thus 'adulterated' under the FDCA." (*Id.* at 5.)

[1] Plaintiffs filed a separate Omnibus Statement Of Law And Generally-Applicable Arguments In Opposition To Bard's Motions To Exclude Plaintiffs' Experts Under Rule 702 And *Daubert* (Doc. 7799). Plaintiffs' Omnibus Statement is not directed at any specific *Daubert* motion Bard filed. As such, Bard does not respond to the Omnibus Statement but instead will address any necessary issues in the context of its individual *Daubert* replies.

- Bard withheld information regarding the Recovery that would "preclude a finding [by the FDA] of substantial equivalence." (*Id*. at 13)

Bard specifically identified the above as examples of impermissible legal opinions *in its own Motion*. (Mot. at 4-5.) Plaintiffs do not argue that the opinions are legal in nature, nor could they. Indeed, Plaintiffs recognize that "as an experienced witness, Dr. Kessler is clearly aware of the difference." (Pl. Br. at 9.) In fact, Plaintiffs did not address these examples at all, other than to confirm that Dr. Kessler intends to offer these opinions at trial.[2] In light of Plaintiffs' unwillingness to abide by their own concession that Dr. Kessler will refrain from offering legal opinions, Bard requests that the Court exclude the legal conclusions and jury instructions identified in Bard's motion and those reiterated above.

**B. The Court Should Exclude Dr. Kessler's Impermissible Factual Narrative.**

Plaintiffs' argument that Bard "mischaracterizes Dr. Kessler's opinions as narrative" flies in the face of the weight of authority Bard cited excluding this type of testimony. Court's routinely prohibit such narratives for good reason: they supplant the orderly presentation of evidence through witnesses with percipient knowledge, they blur the lines between counsel's closing argument and an unbiased expert's analysis, and they usurp the jury's role of drawing inferences from the factual record. Not surprisingly, Plaintiffs do not address many of the argument in Bard's motion, but instead claim that Dr. Kessler's narrative testimony catalogues "the voluminous record" "of Bard's failure to act as a reasonable medical device manufacturer." (Pl. Br. at 11.) This precise argument

[2] The cases Plaintiffs cited are distinguishable. Each permitted the witness to explain FDA regulations as background to for the jury, but prohibited testimony that defendant violated those regulations. *See In re Testosterone Replacement Therapy Prod. Liab. Litig. Coordinated Pretrial Proceedings*, No. 14 C 1748, 2017 WL 1836443, at *15 (N.D. Ill. May 8, 2017) ("The ultimate conclusions a jury will have to draw are rooted in state law, not federal law…That said, the Court agrees with AbbVie that Dr. Kessler may not appropriately testify about the role of state tort liability vis-à -vis the federal regulatory scheme"); *In re Fosamax Prod. Liab. Litig.*, 645 F. Supp. 2d 164, 191 (S.D.N.Y. 2009) (permitting "Dr. Parisian [to testify] about *general* FDA regulatory requirements and procedures") (emphasis added).



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was rejected by *In re Rezulin Products Liability Litigation*, 309 F. Supp. 2d 531, 551 (S.D.N.Y. 2004) (excluding expert who "propose[d] to testify to a narrative reciting selected regulatory events concerning Rezulin, including Advisory Committee meetings, labeling changes, 'Dear Doctor' letters, and approval and withdrawal decisions by regulators in the United States and abroad" claiming it was a "historical commentary of what happened," and rejecting the plaintiffs' argument that this factual narrative "merely forms the basis for his opinions and helps to explain his reasoning to the jury."). The *Rezulin* court excluded the testimony because "'the glosses that [the expert] interpolates into his narrative are simple inferences drawn from uncomplicated facts that serve only to buttress plaintiffs' theory of the case… [he] does no more than counsel for plaintiff will do in argument, *i.e.*, propound a particular interpretation of defendant's conduct." *Id.* (internal quotation omitted).

Moreover, although Plaintiffs claim that this narrative is necessary to explain Dr. Kessler's regulatory opinions, most of Dr. Kessler's testimony is devoid of such analysis. Dr. Kessler's first expert report is 222 pages long. (Mot. Ex. A) Pages 15 to 30 provide a regulatory background section, but do not link those regulations with any particular opinions. (*Id.*) Pages 31 to 213 contain the factual narrative. On pages 214 to 222, the section that Plaintiffs claim is a summary of his opinions, Dr. Kessler does not cite a *single* regulation.[3]

Plaintiffs' attempt to distinguish the cases Bard cited is unavailing. Dr. Kessler's report contains precisely the same "analytical gap" between factual background and regulatory analysis those courts found deficient. *See In re Trasylol Prod. Liab. Litig.*, 709 F. Supp. 2d 1323, 1337 (S.D. Fla. 2010) ("[The regulatory expert] makes no references to

[3] Plaintiffs gloss over Dr. Kessler's own footnote disclaimer, which states "[t]he following list is not meant to be an all-inclusive list of opinions. Please read the report in its entirety." (*Id.* at 214 FN 89). However, the few opinions buried in the factual narrative suffer from the same problem. (S*ee e.g.,* Mot. Ex. A, at pp. 61-63 (without citing any regulations, offering opinions such as "[i]n my opinion, by April 26, 2004, when Bard made a decision to design a new filter to deal with the complications associated with the Recovery Filter, a prudent device manufacturer would not have continued to sell a filter [performing worse] than its predicate.")).

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FDA regulations in her recitation of the foregoing facts and does not tie them to the opinions that they are intended to support."); *id*. at 1347 ("All of [the regulatory expert's] opinions suffer from this fatal flaw: she recounts Trasylol's regulatory history, the contents of Bayer's internal documents and e-mails, and the findings of scientific studies; she then offers a broad opinion, often outside her scope of expertise, that is not connected to the underlying facts in any apparent way and that lacks regulatory expert analysis.") (*citing Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)); *Lopez v. I-Flow Inc*., No. CV 08-1063-PHX-SRB, 2011 WL 1897548, at *10 (D. Ariz. Jan. 26, 2011) ("[The regulatory expert's] report simply presents a narrative of selected regulatory and corporate events and quotations and then leaps to a conclusion without sufficient explanation.").

Furthermore, many other courts have excluded similar narratives. *See, e.g*., *Rheinfrank v. Abbott Labs., Inc*., No. 1:13-CV-144, 2015 WL 13022172, at *9 (S.D. Ohio Oct. 2, 2015), *aff'd*, 680 F. App'x 369 (6th Cir. 2017) ("[The regulatory expert's] commentary on documents and exhibits will be limited to explaining the regulatory context in which they were created, defining any complex or specialized terminology, or drawing inferences that would not be apparent without the benefit of experience or specialized knowledge. She will not be permitted to merely read, selectively quote from, or 'regurgitate' the evidence.") (internal quotations omitted); *In re Mirena IUD Prod. Liab. Litig*., 169 F. Supp. 3d 396, 478 (S.D.N.Y. 2016) ("[The plaintiffs' regulatory expert] writes at length about the regulatory history of Mirena and internal communications among Bayer personnel and between Bayer and the FDA. To the extent [that she] is simply rehashing otherwise admissible evidence about which [she] has no personal knowledge, such evidence—taken on its own—is inadmissible.") (internal quotation omitted).

Lastly, none of the cases that Plaintiffs cite address the fact that, in this case, Dr. Kessler admitted that "[a]ll Schedules were prepared by staff from legal counsel." (Mot. Ex. E, Kessler Dep. I at 80:4-14.) Moreover, Dr. Kessler copied large amounts from those Schedules into his report's factual narrative, including the specific excerpts of Bard's

documents identified for him by Plaintiffs' counsel. Plaintiffs claim that this assertion "is simply wrong, as even a cursory review of those schedules would reveal." (Pl. Br. at 12, FN 8.) Yet Bard has done precisely that, and compiled a chart comparing Schedules 9 and 28, prepared by Plaintiffs' counsel, with the corresponding paragraphs from Dr. Kessler's report, attached as Exhibit A. Even the portions not quoting Bard documents, such as introductory and descriptive phrases, are copied nearly verbatim.

**C. Dr. Kessler's Opinions about Information Allegedly Withheld from FDA and His Rank Speculation about What FDA Would Have Done with Allegedly Withheld Information Should Be Excluded Because They Are Irrelevant and Preempted.**

Plaintiffs gloss over the fact that FDA never removed any of Bard's IVC filters from the market, and never found that Bard violated any FDA regulations. In an attempt to rewrite history, Dr. Kessler speculates that if Bard had disclosed certain information manufacturers *never* customarily submit to FDA, such as internal emails and memoranda, draft testing documents, draft PowerPoint presentations, and other documents that the FDA would not ordinarily review or rely on, then FDA would have taken certain actions. For example, Plaintiffs admit that "Dr. Kessler concludes that if Bard had removed the Recovery filter from the market in April/May 2004, as it should have, there would have been no legally marketed predicate for Bard to have claimed substantial equivalence for a new device." (Pl. Br. at 5 (citing Dr. Kessler's report).) In other words, Dr. Kessler conjures a causal chain dating back to the Recovery. The theory goes that because the Recovery violated the FDCA, Bard should have removed it from the market. If Bard had removed it from the market, then the FDA, *years* later, would not have cleared the G2 filter. The implication, of course, is that G2 plaintiffs would have no injuries had Bard only stopped selling the Recovery. The United States Supreme Court squarely rejected this reasoning and held it preempted. *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2477, 186 L. Ed. 2d 607 (2013) ("We reject this 'stop-selling' rationale as incompatible with our pre-emption jurisprudence. Our pre-emption cases presume that an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in

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order to avoid liability. Indeed, if the option of ceasing to act defeated a claim of impossibility, impossibility pre-emption would be 'all but meaningless.') (internal quotation omitted).

In an attempt to avoid this controlling precedent, Plaintiffs recast this speculation as a discussion of "what a reasonable FDA official would have done." Plaintiffs place Dr. Kessler back at the FDA and tell the jury that he would have taken action had he only known of the information Bard allegedly withheld. This is a distinction without a difference because the claims nevertheless raise the same "fraud on the FDA" allegations rejected in *Buckman Co. v. Pls.' Legal Comm.*, 531 U.S. 341 (2001). Furthermore, Dr. Kessler admitted that he could not recall any involvement with IVC filters while he was employed by the FDA. (October 5, 2016, Deposition of David Kessler, at 20:10 – 21:5, attached as Exhibit B.)

Plaintiffs rely on two cases for this "reasonable FDA official" standard. *In re Diet Drugs Prod. Liab. Litig.*, No. MDL 1203, 2001 WL 454586 (E.D. Pa. Feb. 1, 2001) was decided before *Buckman*. The second case, *In re Yasmin & YAZ (Drospirenone) Mktg., Sales Practices & Prod. Liab. Litig.*, No. 3:09-MD-02100-DRH, 2011 WL 6302287 (S.D. Ill. Dec. 16, 2011) was decided before *Bartlett*. (Pl. Br. 14-15.) And, even assuming this standard was relevant, Dr. Kessler would need more than his *ipse dixit* conclusions, and instead would need to demonstrate FDA standards or procedures supporting his opinions.

More generally, Plaintiffs cite *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 629–30 (S.D.W. Va. 2013), which was also decided before *Bartlett*, and only stated that "Dr. Kessler may testify, for example, that Bard did not disclose certain information to the FDA that Dr. Kessler, as a former Commissioner of the FDA, would have found *pertinent*." (emphasis added). Dr. Kessler opining that he would have wanted to know "X", versus Dr. Kessler opining that Bard violated FDA regulations because the FDA was never told "X", are two very different opinions. The court recognized this in concluding that "Dr. Kessler may not testify that Bard violated FDA regulations—such testimony would be drawing legal conclusions." *Id*. at 629 (excluding opinions such as "Bard *failed*

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*to adequately disclose* adverse risks associated with their products," "Bard *failed to warn* on its label," and prohibiting Dr. Kessler from using any terms that "have a separate, distinct, and specialized meaning in the law.") (emphasis in original).

The weight of authority clearly rejects opinions second-guessing the FDA as preempted or speculative, because "[u]nder Plaintiffs' reasoning, a plaintiff could *always* cite to a particular piece of data, presumably unconsidered by the FDA, and overcome conflict preemption." *In re Incretin-Based Therapies Prod. Liab. Litig.*, 142 F. Supp. 3d 1108, 1130–31 (S.D. Cal. 2015) ("Thus, although Plaintiffs reframe this data as new safety information, the Court declines to consider it as undermining the FDA's conclusion…the Court notes that it remains unclear whether the FDA considered this information, and if it did not, whether this data would have altered the FDA's conclusion. The parties' experts dispute whether the information was material to the FDA's analysis and offer little clarity on this point. However, as noted at the hearing on these motions, it is unlikely that a conflict preemption proponent, or a plaintiff opposing the defense, would ever know the full extent of what the FDA reviewed in evaluating a safety signal….A reevaluation of scientific data or a judicial challenge to the accuracy of the FDA's conclusions would disrupt the 'delicate balance of statutory objectives' the *Buckman* Court sought to preserve.") (emphasis added).

As a result, this Court should exclude such speculative and preempted testimony as numerous other courts have done. *See e.g., Rheinfrank v. Abbott Labs., Inc.*, 119 F. Supp. 3d 749, 767–68 (S.D. Ohio), *aff'd*, 680 F. App'x 369 (6th Cir. 2017) ("Plaintiffs' argument that Abbott withheld certain information or misrepresented the results of studies in its 2005 and 2007 submissions to the FDA appears to be a fraud-on-the-FDA theory, which is preempted…Regardless, an expert's opinion that the FDA would have reacted differently if the submissions to the FDA in 2005 and 2007 had been supported by different evidence is speculative.") (citations omitted); *In re Trasylol Products Liab. Litig.*, No. 08-MD-01928, 2010 WL 4259332, *12 (S.D. Fla. Oct. 21, 2010) ("[An expert] may not speculate as to what the FDA would have done in hypothetical circumstances.");

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*Webster v. Pacesetter, Inc.*, 259 F.Supp.2d 27, 37 (D.D.C.2003) ("Nor can plaintiffs create an issue of fact regarding their defective warning claim by speculating that if the FDA had known of the delayed perforation and tamponade incidents during the clinical trials and *if* defendant had investigated all the adverse incidents, the FDA would have either recalled the [product] or placed it on alert." (emphasis in original)).

**D. Dr. Kessler Is Not Qualified To Opine on IVC Filter Design, Testing, Causation.**

Plaintiffs do not dispute that Dr. Kessler is unqualified to opine about design, testing, or causation. Nor do Plaintiffs address the specific opinions and arguments Bard cited. Instead, Plaintiffs claim that "Dr. Kessler is not offering opinions concerning, for example, whether Bard's filters were defectively designed," and that all of Dr. Kessler's design, testing, and causation opinions fall within his expertise because "they concern regulatory non-compliance." (Pl. Br. at 16.) This logic fails for two reasons. First, Dr. Kessler undoubtedly intends to testify, among other opinions outside his expertise, that Bard's filters were defectively designed. (*See e.g.*, Ex. B, Kessler Dep., at 141:8 – 142:19 (testifying that the "[G2] was clearly defective.")) Second, allowing an FDA expert to opine on everything remotely within the scope of the massive governmental entity would defeat the purpose of Rule 702. Dr. Kessler, who has no expertise in engineering, interventional radiology, blood flow dynamics, or any number of specialized fields that contribute to designing IVC filters, is not qualified to testify as to design, testing, or causation in this case. In fact, by Plaintiffs' reasoning, Dr. Kessler would be qualified to opine on the design, testing, or causation of *every* pharmaceutical or medical device ever marketed. *See e.g., In re Mirena IUD Prod. Liab. Litig.*, 169 F. Supp. 3d 396, 478 (S.D.N.Y. 2016) ("[The plaintiffs' regulatory expert] is not an engineer, nor has she ever designed IUDs, nor does she have any particular expertise in IUDs. [She] is an expert in the field of FDA regulations, and her testimony will be thus limited to that field.").

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**E. Dr. Kessler's Opinions Regarding Corporate Intent and Ethics Are Not Reliable and Would Not Assist the Jury.**

Dr. Kessler pays lip service to the prohibition against expert opinions on ethics, but much like his impermissible legal conclusions, he is determined to render these opinions nonetheless (*See e.g.*, Mot. Ex. F, Kessler Dep. II, at 39:17 – 40:2 ("But not in the ethical -- well, I'll leave others to talk about ethics, whether -- I'm not going to talk about ethics, but I have, again, *considerable concern*…") (emphasis added)) Dr. Kessler's personal "concern" with Bard's conduct is the exact type of corporate conduct opinion that is devoid of any ethical or professional standards analysis, and unrelated to FDA regulations.

Plaintiffs attempt to camouflage these types of corporate conduct opinions with Dr. Kessler's other opinions, including the claim that Bard made misleading statements, which, as discussed above, should also be excluded. (Pl. Br. at 17.) In doing so, Plaintiffs cite to a different portion of *Tillman v. C.R. Bard, Inc.*, 96 F. Supp. 3d 1307 (M.D. Fla. 2015) than that cited by Bard. Importantly, an expert opining that a manufacturer's statement was misleading is a completely different opinion than divining Bard's intent or concluding that Bard acted unethically, and Plaintiffs confuse the issue by claiming that Bard "misleadingly" cited *Tillman*. *Compare id.* at 1326 (excluding the opinion that "'Bard was *fully aware* that its claims regarding improved fatigue resistance for the G2 filter were false, misleading and reckless'" because the experts "do not purport to have any expertise on the relevant ethical or professional standards, and they do not identify the ethical or professional standard on which they base this opinion,") *with id.* at 1327 (allowing "[a]n opinion that Bard's claim was misleading because it was not supported by the tests performed" because the experts "reviewed the testing done to support Bard's claim" and the opinion "does not relate to legal standards, nor is it a question of Bard's state of mind or intent.") (emphasis added).

In any event, Plaintiffs do not address the examples cited in Bard's motion, such as Dr. Kessler's intent to tell the jury that Bard did not act as "a reasonably prudent manufacturer." (Mot. at 6-7.) Plaintiffs also do explain how many of Dr. Kessler's other

intent and ethics opinions throughout his factual narrative have any relationship whatsoever to FDA regulations, including that Bard's "iterative process [through multiple generations of filters] put patients at risk" and that "Bard was 'beta testing' its IVC filters in patients." (Pl. Br. at 5 (citing Dr. Kessler's Report)). Thus, Dr. Kessler's opinions regarding Bard's state of mind and corporate ethics should be excluded.

## CONCLUSION

Dr. Kessler's opinions are not only inadmissible under Rule 702, but are also unhelpful and unreliable under *Daubert*. Accordingly, the Dr. Kessler's opinions should be excluded in their entirety.

Respectfully submitted this 18th day of October, 2017.

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**CERTIFICATE OF SERVICE**

I hereby certify that on October 18, 2017, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send email notification of such filing to all attorneys of record.

s/Richard B. North, Jr.
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